WITHDRAWAL OF APPROVALS

I. Purpose:

This guide describes actions undertaken by CVM which may affect products previously approved by FDA.

II. Withdrawal of NADA Approval:

A. Authority. The FD&C Act (Section 512(e), 512(m)) provides certain grounds on the basis of which approval of an NADA may be withdrawn.

B. Approval of an NADA is withdrawn on findings that:

1. The drug is unsafe. Clinical or other experience, tests, or other scientific data show that the drug is unsafe under the approved conditions of use.

2. The drug is not shown to be safe. New evidence of clinical experience or tests by new methods or tests by methods not deemed reasonably applicable when the NADA was approved, evaluated with the evidence available when it was approved, show that the drug is not shown to be safe under the approved conditions of use.

3. Substantial evidence of effectiveness is lacking. New information, evaluated together with evidence available when the NADA was approved, shows a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use recommended in the labeling.

4. An untrue statement of material fact is contained in the NADA.

5. Required records have not been maintained or reports submitted.

6. Inadequate controls. New information, evaluated with evidence available when the NADA was approved, shows that the methods, facilities, or controls used in the manufacture, processing, and packing of the drug are inadequate to assure and preserve the identity, strength, quality, and purity of the drug.

7. False and misleading labeling. New information, evaluated with information available when the NADA was approved, shows that the labeling is false and

misleading.

8. The applicant has made change(s) from the standpoint of safety or effectiveness beyond the variation provided for in the application unless the changes are covered by an approved supplemental application or permitted under section 514.8(d) and (e).

C. Grounds (6) and (7) above may only serve as basis for withdrawal of approval if the applicant has failed to correct the deficiencies within a reasonable time after being notified of them.

D. Procedure:

1. An applicant must be given an opportunity for a hearing on the proposal to withdraw approval.

   a. Sometimes the applicant is advised of our intention and requests that approval be withdrawn without a hearing.

   b. Unless the applicant requests withdrawal, a Notice of opportunity of Hearing on the proposal to withdraw approval is published in the FEDERAL REGISTER.

   c. A request for withdrawal of approval by the sponsor of the application under the provisions of 21 CFR 514.115(d) is construed as a waiver of the opportunity for a hearing.

2. If the applicant waives the opportunity for a hearing, a final order is published in the FEDERAL REGISTER withdrawing approval of the NADA except that a Form FD 1900 for a medicated feed may be withdrawn by letter. The Center Director is delegated this authority.

3. A request for a hearing must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If upon review of the facts a hearing is not justified, the Commissioner will enter a summary judgment requiring withdrawal. If a hearing is justified, an administrative law judge will be named to conduct the hearing.

4. The decision to deny a hearing may be appealed in Federal Court.

E. Special procedure. If there is an imminent hazard to health, the Secretary of Health and Human Services is empowered to suspend approval of the NADA immediately. An

expedited hearing is to follow.

III. Revocations Affecting Drugs:

See Guide 1240.3670 regarding Management of Formal Evidentiary Hearings.

IV. Voluntary Withdrawal of Applications:

Sponsors of a pending NADA or FAP or of an approved NADA may voluntarily withdraw their application upon written notification to FDA. Such withdrawals may be made without prejudice to future filings. The procedure for handling submissions related to withdrawals is as follows:

A. Requests for withdrawal of pending NADAs as provided for under 21 CFR 514.7 will be processed in the appropriate review Division in NADE. Requests for withdrawal of pending FAPs as provided for under 21 CFR 571.7 will be processed by the Division of Animal Feeds (HFV-220). (Those NADAs or FAPs that are pending and have not received final approval.)

B. Requests for withdrawal of approved NADAs as provided for under 21 CFR 514.115(d) will be processed in the Division of Epidemiology and Surveillance (HFV-210).